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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
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| 09/435,249 | 11/05/1999 | JAY S. SCHNEIDER | SCH01.NP001 | 4962 |

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| EXAMINER |
|---|
| SCHMIDT, MARY M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1635 | |

DATE MAILED: 12/24/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| Advisory Action | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/435,249 | SCHNEIDER, JAY S. | |
| | Examiner | Art Unit | |
| | Mary M. Schmidt | 1635 | |

*--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search. (see NOTE below);

   (b) ☐ they raise the issue of new matter. (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see section 11 (Other) below*.

4. ☐ Applicant's reply has overcome the following rejection(s): _____.

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

6. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☐ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-22*.

   Claim(s) withdrawn from consideration: _____.

9. ☐ The proposed drawing correction filed on _____ a)☐has b)☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s)( PTO-1449) Paper No(s). _____.

11. ☒ Other: *See Continuation Sheet*

Continuation of 11. Other: Amendment B was not entered in view of the addition of specific antisense targets appearing in claims 1 and 9. The inclusion of the specific targets requires a further search of the prior art for those specific targets. The amendment to claims 1-22 reduces the 35 U.S.C. 112, first paragraph, scope of enablement issues by narrowing the claims to the specific SEQ ID NOS. enabled and the specific routes of administration enabled by the specification as filed. However, The proposed addition of claims 23-33, which are broadly drawn to administration of any antisense to whole organisms, further raises 35 U.S.C. 112, first paragraph, enablment issues for the same reasons argued in the Official Actions mailed 03/30/00, 01/03/01 and 08/13/01. Applicant argues in the response filed 11/13/01 that "because administration of any oligonucleotide to the target nucleic acid will inhibit, to varying efficiencies, the expression of the target, new claims 28-33 are enabled. No amount of undue experimentation is required to practice the claimed invention." However, as argued in the prior Offical Actions, there is a high level of unpredictability in the art for administration of antisense to whole organisms. The teaching of in vivo administration of one antisense to a whole organism does not correlate to an expectation of success for in vivo efficacy of any antisense compound, even when the compound targets the same gene target. Furthermore, although the prior art taught potential animal models for human Parkinson's disease, it is unclear whether or not administration of a therapeutic agent such as those claimed to the animal models correlates to administration of the same therapeutic agents to all mammals, especially humans. Thus it is unclear whether the disclosed animal models enable the scope of the mammals broadly claimed for treatment of Parkinson's disease.

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